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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,419	05/09/2008	Claus Frohberg	65084.000020	1422

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EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,419	FROHBERG ET AL.	
	Examiner	Art Unit	
	BRENT PAGE	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-35* is/are pending in the application.

4a) Of the above claim(s) *9-18 and 26-35* is/are withdrawn from consideration.

5)☒ Claim(s) *1,6-8,19-21 and 23-25* is/are allowed.

6)☒ Claim(s) *5 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/2006, 11/2006, 11/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 5-8 and 19-25 in the reply filed on 10/18/2010 is acknowledged. The traversal is on the ground(s) that the Inventions share a technical feature not identified by the Examiner, and further, that the restriction is based off features of dependent claims (see pages 7-10 of response). This is not found persuasive because Applicant is entitled to a first product, a method of making said product and a method of using said product. The claims as currently written encompass multiple products, proteins, nucleic acids, plants and plant cells. The instantly claimed methods are drawn to a method of identifying a protein and the proteins isolated using said method. The nucleic acids are not required to isolate said proteins, may be used for materially different purposes, and require method steps not required in the isolation of the protein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, and 5-35 are pending. Claims 9-18 and 26-35 are withdrawn as being drawn to nonelected subject matter. Claims 1, 5-8 and 19-25 are examined herein on the merits.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There are numerous embedded hyperlinks in

the specification, 2 in paragraph 111, 1 in paragraph 112, 2 in paragraph 243, 3 in paragraph 289, 1 in paragraph 339, 1 in paragraph 340, 1 in paragraph 341, 1 in paragraph 342, and 1 in paragraph 372. There are Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claim is drawn to any protein obtainable by the method of claim 1. The specification only describes OK1 proteins, and does not describe any other proteins that bind preferentially to phosphorylated alpha-glucans, nor does the specification describe what features of the OK1 protein are required for this preferential binding.

The genus encompasses literally countless numbers of potential proteins with countless numbers of functions. The only working examples involve OK1 proteins, a single type of protein out of a genus that encompasses literally millions of proteins and

isoforms of proteins. Consequently, the instant specification does not describe a representative number of working examples for this extremely large genus.

In the absence of a representative number of working examples, the specification is required to at least describe the structural features that are required for function (ie preferentially binding phosphorylated alph-glucans). The specification does not describe which sequences are absolutely required for this function or are likely to be conserved across proteins with a different function.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112-enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins with alpha-1,4-glucan phosphorylating activity, does not reasonably provide enablement for any other polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is drawn to any protein obtainable by the method of claim 1. While practicing the method of claim 1 is enabled, the specification does not provide guidance as to what other proteins might bind to phosphorylated alpha glucans, does not identify any proteins other than proteins termed "OK1" proteins, and does not teach one of skill in the art how to use any such other proteins.

In the instant case, the specification does not teach one of skill in the art how to use any protein other than an OK1 protein, and thus, is not enabled for proteins that do not have such activity.

It is suggested that to overcome this rejection that the activity of the protein be recited in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kikuchi et al (US20060123505, filed May 29, 2003).

The claims are drawn to any protein and any protein with alpha-1,4-glucan phosphorylating activity, respectively that may be identified by the instantly claimed method.

Kikuchi et al teach the transformation of a host cell and regeneration of a plant with SEQ ID NO:22133 which encodes the OK1 protein from rice. The resultant protein, inherently would be obtainable by the described methods.

Claims 1, 6-8, 19-21 and 23-25 appear to be free of the prior art given the failure of the prior art to teach or reasonably suggest a method of identifying a protein wherein the unknown protein is bound to both phosphorylated and non-phosphorylated alpha-1,4-glucans and isolated based on an increase binding to phosphorylated alpha-1,4-glucans. The closest prior art appears to be Lorbeth et al (1996 Nature Biotechnology 16:473-477). However, Lorbeth et al do not measure the proteins that bind preferentially to phosphorylated alpha-1,4-glucan, but rather, measure the phosphorous content of starch bound to protein. It is also noted that the method of Lorbeth et al does not involve the dissolving of proteins not bound to the starch and the isolation of the protein on that basis. Thus, claims 1, 6-8, 19-21and 23-25 appear to be allowable subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent Page
Examiner
Art Unit 1638

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